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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,719	04/30/2007	Sheetal Mansukhlal Shah	70397	5346

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Syngenta Crop Protection, Inc.,
Patent and Trademark Department
410 Swing Road
Greensboro, NC 27409

EXAMINER

HIRIYANNA, KELAGINAMANE T

ART UNIT	PAPER NUMBER
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1633

MAIL DATE	DELIVERY MODE
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02/14/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/597,719	Applicant(s) SHAH ET AL.	
	Examiner KELAGINAMANE HIRIYANNA	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 November 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5 and 6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 5 and 6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date. _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's response filed on *11/30/2010* in response to office action mailed on 08/31/2010 has been acknowledged.

Claims 1, 3, 5 and 6 are amended.

Claims 2 & 4 are cancelled.

Claims 1, 3, 5 and 6 are pending and presently under examination.

*Applicants are required to follow Amendment Practice under revised 37 CFR §1.121. The fax phone numbers for the organization where this application or proceeding is assigned is **571-273-8300**.*

Withdrawn: Objections to claims and specification for the reasons of record as set forth in the office action mailed on 08/31/2010 are withdrawn in view of Applicants amendments.

Withdrawn: Claim 2 rejection under 35 U.S.C. 112, second paragraph f or the reasons of record as set forth in the office action mailed on 08/31/2010 are withdrawn in view of Applicants cancellations to cited claim.

Withdrawn: Claims 1, 3, 5 and 6 rejection under 102(b) as being anticipated by Lam et al., (2000, Current Biology 10:957-963) for the reasons of record as set forth in the office action mailed on 08/31/2010 are withdrawn in view of Applicants amendments or cancellations to cited claims and in view of new rejection .below.

Withdrawn: Claims 1, 3, 5 and 6 rejection under 35 USC 103 (a) as being unpatentable over Lam et al., (2000, Current Biology 10:957-963) in view of Fisk et al (proc. Natl. Acad. Sci. USA 92:10604 -10608) and Kalidas, et al. (2002, Neuron, 2: 177-84) for the reasons of record as set forth in the office action mailed on 08/31/2010 are withdrawn in view of Applicants amendments or cancellations to cited claims and in view of modified rejection .below.

Withdrawn: Claims 1-3, 5, and 6 rejection under 35 U.S.C. 103(a) as being unpatentable over Capecchi, et al. (1994) Scientific American, 270: 34-41 (art of record)

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and Fisk, et al. (1995) Proceedings of the National Academy of Sciences, USA., 92(23): 10604-608; and Kalidas, et al. (2002) Neuron, 2(17): 177-84 for the reasons of record as set forth in the office action mailed on 08/31/2010 are withdrawn in view of Applicants amendments or cancellations to cited claims and in view of a modified rejection .below..

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, 5 and 6 are rejected under 102(e) as being anticipated by Thummel et al., (WO 2005/069859 A2; Priority date: 13 Jan 2004).

The above claims are drawn to a transgenic insect or insect cell wherein the level of expression of dhr96 or homologue thereof has a reduced relative to the level of expression of dhr96 or its homologue in a non-transgenic insect or non-transgenic insect cell wherein the homologue encodes a protein having at least 95% identity to D .melanogaster dhr96 gene. In further limitations transgenic insect is a Drosophila sp, in still further limitation the expression of said dhr96 or said dhr96 homologue has been reduced through RNAi.

Thummel teaches a method of reducing the expression of dhr96 gene in a Drosophila species that is transgenic by targeted mutagenesis or knockout of the dhr96 gene (entire article; abstract; p.1, lines 29-32 bridging p.2; p.15-18; p.20-22; p.43). Further disclosed are these transgenic mutants which have reduced DHR96 activity and also disclosed are the compositions capable of inhibiting DHR96 activity (p.7, lines 8-16; p.22-23). Still further disclosed is the use of RNAi to reduce the DHR96 activity (p.18 lines 28-30; p.23-27).. The cited art thus clearly anticipates the invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, 5 and 6 are rejected under 35 USC 103 (a) as being unpatentable over Lam et al., (2000, Current Biology 10:957-963; art of record) in view of Fisk et al (proc. Natl. Acad. Sci. USA 92:10604 -10608; art of record) and Kalidas, et al. (2002, Neuron, 2: 177-84; art of record) and Kozlova, et al. (2003) Methods in Enzymology, 364: 475-490; art of record)

The above claims are drawn to a transgenic insect or insect cell wherein the level of expression of dhr96 or homologue thereof has a reduced relative to the level of expression of dhr96 or its homologue in a non-transgenic insect or non-transgenic insect cell.

Lam teaches a method of reducing the expression of ecdysone receptor (a functionally related nuclear receptor to dhr96) in a Drosophila species that is transgenic for the dsRNA expression construct by the way of RNA interference and the cells derived from the same were also had the reduced cellular levels of EcR expression (entire article; abstractp.961-962). Lam however, does not teach dhr96 and Drosophila melanogaster.

Regarding claims Fisk teaches cloning and expression of dhr96 gene and its several of its homologues from Drosophila.

Kalidas teaches that using cDNA of gene one can generate a knockdown of the expression of a Drosophila melanogaster's genes by the method of RNA interference. Kalidas also teaches using knockout methods for generating the same (p.177).

Kozlova, describes several methods of knocking-out nuclear receptors in drosophila (e.g., pp. 484 et seq.).

Thus it would have been obvious for one of ordinary skill in the art to substitute a generic gene or cDNA in the expression constructs for RNAi interference method of Lam or Kalidas with the dhr96 cDNA and express the dhr96iRNA in Drosophila melanogaster and reduce levels of expression of dhr96 in said transgenic Drosophila melanogaster as

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compared to its expression in wild type *Drosophila melanogaster*. One of ordinary skill in the art would have reasonable expectation of success making using a transgenic *drosophila* with a relatively reduced level of expression of *dhr96* or its homologue because the art teaches it is routine use RNA interference or knockdown or knockout of a targeted gene in order to reduce its expression in the transgenic organism or a cell. Thus, the claimed invention was *prima facie* obvious.

Response to Applicants argument of 11/30/2010:

Applicant amends the claims and argues that the invention is not obvious over prior art cited as each of the references cited do not teach all the elements of the invention.

The Applicants arguments are however found not persuasive because the combinations of the cited prior art in the light of relevant prior art knowledge available to the skilled Artisan at the time of invention clearly encompassed all the elements of the invention claimed. The Applicant further should note that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. "The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art." Hence the rejection as indicated above is maintained.

Conclusion

No claim allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Kelaginamane Hiriyanne Ph.D.*, whose telephone number is **(571) 272-3307**. The examiner can normally be reached Monday through Thursday from 9 AM-7PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Joseph Woitach Ph.D.*, may be reached at **(571) 272-0739**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). When calling please have your application serial number or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. For all other customer support, please call the USPTO call center (UCC) at (800) 786-9199.

/Robert M Kelly/

Primary Examiner, Art Unit 1633